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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,791	07/25/2003	Steve Bigus	ACS 64940 (2238D)	2675
24201 7590 05/22/2008 FULWIDER PATTON LLP HOWARD HUGHES CENTER 6060 CENTER DRIVE, TENTH FLOOR LOS ANGELES, CA 90045				
EXAMINER PREBILIC, PAUL B				
ART UNIT 3774		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/627,791

Applicant(s)

BIGUS ET AL.

Examiner

Paul B. Prebille

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1.5-11 and 20-34 is/are pending in the application.
- 4a) Of the above claim(s) 8-10, 22, 23 and 31-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1.5-7, 11, 20, 21 and 24-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Election/Restrictions

Claims 8-10, 22, 23, and 31-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 19, 2006.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5-7, 11, 20, 21, and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The new language "entirely affixed" (see claim 1, line 7) does not have original support from page 4, lines 24-25 and Figure 10 as alleged so it is considered new matter. In fact, Figure 10 shows the filament spaced from and apparently unfixed to the prosthesis. Claims 5-7, 11, 20, 21, and 24 are dependent upon claim 1 so they also contain new matter by incorporating the language of claim 1 therein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1, 5-7, 11, 20, 21, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In view of the specification and the Applicant's remarks, it is not clear what the terminology "entirely fixed" denotes. However, to give this terminology its broadest reasonable interpretation, the Examiner will interpret it to mean that the biocompatible material is affixed to the endoprosthesis at the ends and along the length where it contacts the endoprosthesis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5-7, 11, 20, 21, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Lenker et al (US 5,843,158) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lenker et al (US 5,843,158) in view of Kocur (US 6,350,277).

Lenker meets the claim language where:

(1) the catheter as claimed is catheter (30) of Lenker;

(2) the expandable member as claimed is balloon (78) of Lenker;

(3) the endoprosthesis as claimed is the frame (12) of Lenker, and

(4) the biocompatible material as claimed is reinforcement element (102); see the Figure 5C and column 6, line 61 et seq. In Figure 5C, the biocompatible material is considered "tightly fitted over the endoprosthesis" as claimed. In addition, the terminology "entirely affixed" is considered met because no part of element (102) is loose from the endoprosthesis and the biocompatible material is affixed to the endoprosthesis at the ends and along the length where it contacts the endoprosthesis.

Alternatively, one may not view the language "entirely affixed" as being met by the structure of Lenker because the biocompatible material is not affixed to a structure in part of the length thereof. However, Kocur teaches that it was known to affix similar biocompatible materials to the endoprosthesis along its length in that the biocompatible material (i.e. retaining segment 115) is affixed to some structure, either the endoprosthesis or to another segment (115), along its length; see Figure 9 and column 5, line 66 to column 6, line 4. Therefore, it is the Examiner's position that it would have been at least obvious to affix the biocompatible material of Lenker to another biocompatible material on the opposite surface, as taught by Kocur for the same reasons that Kocur does the same.

With regard to claim 7, welding as disclosed by Lenker is a form or type of heat bonding (see column 9, line 44 of Lenker).

With regard to claims 20 and 21, the thinner diameter portion as claimed is that portion of filament (102) not at the attachment points; see Figure 5D for the narrower diameter portions, where the larger diameter portions are at the attachment points.

Claims 25 to 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al (US 5,843,158) in view of Kocur (US 6,350,277). Lenker meets the claim language as explained in the Section 102 rejection *supra* but fails to teach making the heat bond such that it fails during expansion of the stent. However, Kocur teaches that it was known to make heat bond points such that failure occur thereat; see column 6, line 5 et seq. as well as Figures 5a to 5c, 10, and 11d, and see column 4, line 18 et seq., column 5, line 18 et seq. and column 7, line 62 et seq. In particular, Kocur teaches that the retaining segments (115) can be attached to the struts (120) by heat, solvent or adhesive (see column 6, lines 2-4) and that the heat bonded biodegradable material can fail due to their biodegradation; see column 6, lines 12-17 and column 7, lines 62-66. Therefore, it is the Examiner's position that it would have been *prima facie* obvious to an ordinary artisan to make the filament (102) of Lenker to fail at the bonding point, as taught by Kocur, for the same reasons that Kocur does the same.

Response to Arguments

Applicant's arguments filed February 14, 2008 have been fully considered but they are not persuasive.

On page 7 of the response, the Applicant argues that the term "nominal" has a special definition on page 16, lines 12-20 of the present specification. However, upon review of the specification, the Examiner could find no definition for the term "nominal"

of any other term. It was noted that "nominal" was used in a manner inconsistent with the ordinary definition of the term that means small and insignificant.

A special definition must be clear, precise and deliberate; see MPEP 2111.01 IV and 2173.05(a) III that are incorporated herein by reference. In particular, there is no special definition for "nominal" in the specification and it not clear what meaning this term is intended to have.

"One purpose for examining the specification is to determine if the patentee has limited the scope of the claim.' . . . For example, an inventor may choose to be his own lexicographer if he defines the specific terms used to describe the invention 'with reasonable clarity, deliberateness, and precision.' Such as definition may appear in the written description" Teleflex, Inc. v. Ficosa No. Am. Corp., 63 USPQ2d 1374, 1381 (Fed. Cir. 2002)

In addition, the Applicant argues that the term "weld" requires that both materials melt. However, this argument does not agree with the broadest reasonable definition of the "weld" that means to join thing (i.e. metals) together with the application of heat or "to bring into close association, bring together as a unit" (American Heritage Dictionary, Second Collage Edition).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/
Paul Prebilic
Primary Examiner
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